**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA

Plaintiff,

v.

B4B EARTH TEA LLC, a limited liability company;

B4B CORP., a corporation; and

ANDREW MARTIN SINCLAIR, individually and as an officer of B4B EARTH TEA LLC and B4B CORP.,

Defendants.

**Civil Action No.: 22-CV-1159**

# EXPERT REPORT OF DR. JAMES P. MCCORMACK

## I. SUMMARY OF QUALIFICATIONS

1. I have been a professor at the University of British Columbia since 1986 and I also worked as a pharmacist in Internal Medicine and Infectious Diseases at St. Paul's Hospital in Vancouver for 20 years. I received my undergraduate pharmacy degree (BSc Pharm) at the University of British Columbia in Vancouver in 1982 and my doctorate in pharmacy (Pharm.D.) in 1986 from the Medical University of South Carolina in Charleston, South Carolina.

2. I have over 140 publications in peer-reviewed journals including high profile journals like the British Medical Journal, Clinical Infectious Disease and the Lancet. I have 3 publications specifically related to COVID-19 treatments and prevention. One a systematic review of azithromycin/hydroxychloroquine, one on assessing shortness of breath in COVID-19 patients and finally a systematic review of the evidence around masks and viral infections. My publications during the last 10 years are listed in Appendix B.

3. The research and evidence appraisal group I work with - PEER (peerevidence.ca) – has published 20 different evidence appraisals on COVID-19 related interventions over the last 2-3 years. I was an author on 2 of these but also reviewed a number of them. I have had extensive experience, both locally and internationally, speaking to health professionals and consumers about the rational use of medication, and have presented over 500 seminars on drug therapy over the last 30 years. In particular, I have been asked to speak on treatments for COVID-19 at 3 different national conferences. In 2013, I received the Association of Faculties of Pharmacy of Canada National Award for Excellence in Education, the highest award for pharmacy teaching in Canada.

4. I am also the co-host of one of the most popular primary care podcasts in the world – the Best Science (BS) Medicine podcast – therapeuticseducation.com. Over the last 2-3 years, I and my co-host have released 13 30-minute podcast episodes on COVID-19-related

topics where we reviewed and critiqued a number of different COVID-19 vaccines and treatments.

5. I have also been an editor on 2 internationally recognized textbooks on therapeutics (Drug Therapy Decision Making Guide and Therapeutic Choices) and recently published a lay-public book (The Nutrition Proposition) where I did an appraisal of hundreds of nutrition related publications.

6. I have not received any funding from any drug companies in over 30 years.

7. Based upon my education, training, research, and my scientific writing and editorial and review experience, as summarized above, I consider myself an expert in the field of evidence appraisal, which covers the design, conduct, analysis, and interpretation of clinical trials. I believe my academic background and experience make me particularly well-suited to evaluate evidence from clinical trial reports and publications, including evidence specifically relating to the clinical efficacy of interventions for COVID-19 and its main symptoms.

8. I have not testified as an expert at deposition or at trial in any other matters in the last 4 years.

9. I am compensated at the rate of $300 per hour for my work relating to this case.

## II. SCOPE OF REPORT, MATERIALS REVIEWED, AND SUMMARY OF CONCLUSIONS

10. For this report I was asked by the U.S. Department of Justice to do the following: For B4B Earth Tea determine and explain if there is any competent and reliable scientific evidence to substantiate the health claims the defendants have made regarding COVID-19 or any other diseases.

11. To render my opinion, I relied on my personal experience and expertise, the materials identified in Appendix A, and the literature search described in paragraphs 33-34

below. As I describe below, the literature search did not return any documents beyond those provided to me by the U.S. Department of Justice.

12. In my opinion, based on my personal experience and expertise, my literature search, and my review of the materials provided to me by the U.S. Department of Justice, there is no competent and reliable scientific evidence to support any claims that Earth Tea provides any of the health benefits claimed by defendants in the marketing materials I reviewed. As I explain in detail below, to support claims that Earth Tea can treat, cure, or prevent COVID-19, or treat or cure any other health condition, qualified experts in the field would require at least one, if not more, controlled, randomized, double-blind human clinical trials. The one publication produced by defendants falls far short of this standard.

## III. DEFENDANTS' HEALTH CLAIMS

13. I first reviewed the roughly 300 social media and website posts provided by the U.S. Department of Justice. These posts contained a variety of health claims made by Andrew Martin Sinclair about Earth Tea. The following is an overview of the claims made - words in " " are direct quotes.

### a. COVID-19 claims

- "We're over Covid19 we are the Best against COVID 19." USA-B4B00005241, 3/1/2022 Twitter post from Head Gone @headgone
- "Again we will say..We have the answer for COVID 19 help us tell the government and scientists stop wasting Money and build on what we have.." USA-B4B-00003193, 2/2/2021 All My Tweets, @b4bcorpusa
- "Proof a natural approach can work but Bias is the reason why people are dying a pill works the very same way Earth Tea Extra Strength works and Earth Tea Extra Strength is 100% effective against Covid19. Earth tea Extra Strength prevents death and stop

COVID 19" USA-B4B-00005231 1/17/2022 Twitter post from Head Gone @headgone Replying to @GovCanHealth

- "They're getting closer and closer to accepting that Earth Tea Extra Strength is the Answer for Covid19. The only 100% option and the World's first Instant Immune Booster" USA-B4B-00004920, 1/21/2022, TWITTER POST, @headgone Replying to @motherboard"
- "100% effective against Covid19 and works extremely fast literally within minutes it will start the reversing process" USA-B4B-00004909, 1/18/2022, TWITTER POST, @headgone Replying to @motherboard
- "We are the first successful plant based company, Find me a plant based product that's guaranteed to help with issues. One that's 100% guaranteed it's used with 100% success" USA-B4B00003786, 3/22/2023, TWITTER POST, @EarthTeabyB4B replying to @wendellsherk and @truth_in_number
- "Earth Tea Extra Strength, it's [sic] works extremely fast and it's 100% effective against Covid 19" USA-B4B00003244, 11/21/2021 Twitter post from Head Gone @ Earth Tea
- "Please help us prevent 900,000 US death from #covid19. If you're positive grab 2 bottles the. The moment you get your result or start feeling symptoms order 2 bottles right away EarthTea.Us our volunteers all reported success you will start feeling better within 2 Hrs." USA-B4B00003300, 12/23/2021 Twitter post from B4B Earth Tea LLC
- "We can form a unified group with the message. Earth Tea Extra Strength works 100% and is more effective than the vaccines for recovery, It works fast 24-48 HRS 2 bottles guaranteed! 100% clinical study and volunteers all recovered 100%." USA-B4B00003288, Twitter Post from @headgone 12/22/2021

- "Earth Tea can make Cruise ships safer. If everyone who boards a cruise ship drinks 1 bottle of Earth Tea before boarding that will keep #Covid19 off board, With Earth Tea on board on ice if it do gets onboard Earth Tea can quickly control it with backup bottles onboard," USA-B4B-00003204, Twitter Post, Covid19 Stopper Movement @b4bcorpusa to @CDCgov, 10/1/2020
- "To this day Earth Tea is the most effective Treatment against#COVID19 as Treatment and Prevention. All NaturAl.. #TRYEARTHTEA Get well in 24-48 hours..72 Hours MAX" USA-B4B-00003146, 10/9/2020, Twitter Post, Covid19 Stopper Movement @b4bcorpusa
- "Honestly this could have ended the Pandemic 'if' the FDA had just listened to me or took me serious... Date April 2020 I told the FDA I have something natural that works 100%" USA-B4B00001939, B4B EARTH TEA, (Plant Based Movement) @EarthTeaOutlet Replying to @danaparish and @CDCgov, 12/8/2022
- "For the last Time!! Try EARTH TEA EXTRA STRENGTH AGAINST COVID19. IT'S THE ONLY 100% GUARANTEED NATURAL OPTION THAT WILL TOTALLY GET COVID OUT OF YOUR SYSTEM AND PREVENT LONG TERM DAMAGE . . . ." USA-B4B00004906, Twitter post, @headgone, 1/17/2022

**b. Publication claims**

14. In these social media posts, there is also a discussion of the findings of a publication authored by Martin Sinclair.

- "Our Clinical Trials documents to be published soon! Stay Tuned!! CLINICAL TRIAL #1 COMPLETED 15 patients tired [sic] Earth Tea Extra Strength 8oz cold during the day then 8oz hot before bed then tested 48hrs after.. 15 people who was tested positive

tried Earth Tea Extra Strength 16oz bottle they took 8oz cold during the day and then 8oz hot before bed. They were then tested 48hrs after and the result is 14 came back with Negative and 1 came back positive. We accept the result but we are Skeptical about that 1 that came back positive we requested video of each bottle before dosing and we were not provided the video, From internal study if 1 bottle won't do 2 or :3 will get rid of Covid19 'guaranteed' this proves Earth [Tea]." USA-B4B-00003652, Instagram post, from b4bearthteallc, 10/13/2021

- "Earth Tea Extra Strength is not a cure or Treatment for no one disease or issue Earth Tea Extra Strength is a Plant Based immune support drink that supports the Immune system. Your immune system then performs the miracles how it knows best." USA-B4B00001803, Twitter post, B4B EARTH TEA..(Plant Based Option), 11/15/2022

**c. Other health claims**

- "Ladies and Gentlemen My tweets are not claims. They are feedbacks from people who tried my product. . . . . I'm not claiming it is a treatment or cure[.] It's an immune support drink." USA-B4B00001634, Twitter Post, B4B Earth Tea @EarthTeaOutlet, 11/10/2022
- "[H]ere's a long living tip my plant based drink. Why? Success with Prostate, colon, cancer, pain and many more!" USA-B4B00002686, Twitter post, B4BEARTH TEA LLC, 1/12/2023
- "I've received successful Feedbacks with COVID[,] PROSTATE[,] ARTHRITIS PAIN[,] CANCER[,] HIV[,] DIABETES and many more with my Plant Based drink . . . ." USA-B4B00001931, Twitter post, B4B Earth Tea @EarthTeaOutlet, 12/7/2022
- "Earth Tea Extra Strength Updates and Feedbacks . . . . tachycardia – irregular heart beat

seems to normalize[,] joint pain – numerous reports about pain relief . . . asthma – less use of pump after Earth Tea use . . . . diabetes . . . most people report feeling ease from issues they normally have from diabetes . . . gastroenteritis relief starts in minutes. Earth Tea Extra Strength instantly start push bad stuff out of your system . . . .” USA-B4B00003413, B4B Earth Tea LLC website, 10/8/2021

- “We received updates from our #1 volunteer who tried 4 Bottles of our Immune drink Earth Tea Extra Strength for 7 Days against stage 4 Colon Cancer. His Blood work now shows Complete Remission which means no cancer cell present in his blood. That’s Amazing New!! [sic]” USA-B4B00000650, b4bearthtea.com website , 10/17/2022
- “Celebrate our First Cancer success story with Us .. cancer cell gone after 2 Bottles of Earth Tea Extra Strength the World’s first Instant Immune Booster. . . someone who had stage 2 breast cancer and after doing her blood work her blood shows no cancer cell.. AMAZING!!!!” USA-B4B00003222, Twitter post, @headgone, 10/25/2021
- “We have a steady winning streak with Prostate. If anyone out there having prostate issues our Natural Immune Booster may help you avoid surgery.” USA-B4B00005201, Twitter post, @b4bearthteallc, 3/13/2022
- “All Natural Covid19 Treatment made by B4B Corp. Also been tested for other health issues.. so Far doing well against Asthma, Lupus and Tachycardia.” USA-B4B00007360, Instagram post, hgmotorcorp “Earth Tea,” 12/9/2020
- “We are seeing amazing results where issues are completely reversed and normalcy is restored.” USA-B4B-00004840, B4B Earth Tea LLC, 3/4/2022
- “The World's first Instant Immune Booster Works instantly and works fast” USA-B4B-00003230, Head Gone, @headgone, 10/24/2021

## IV. TYPE OF EVIDENCE REQUIRED TO SUBSTANTIATE DEFENDANTS' HEALTH CLAIMS

15. The U.S. Department of Justice has asked me what kind of evidence experts in the field of evidence appraisal would require to substantiate defendants' health claims. For purposes of analyzing what evidence is required to substantiate defendants' health claims, and evaluating whether there exists evidence to substantiate defendants' health claims, I will group the health claims discussed in Section III into two categories.

16. The first category covers claims that Earth Tea can treat, cure, or prevent COVID-19, which I understand to include claims that Earth Tea can lead to recovery from COVID-19 in a certain time period (e.g., 24 or 48 hours), claims that Earth Tea can prevent or reduce the risk of hospitalization, and claims that Earth Tea can treat any of the symptoms associated with COVID-19. I also understand this to include any comparative claims about Earth Tea as a treatment or cure for COVID-19, such as that Earth Tea is as or more effective than any vaccine in treating or preventing infection from COVID-19, and claims about the existence of clinical evidence showing that Earth Tea is effective as a treatment or cure for COVID-19.

17. The second category covers claims that Earth Tea can treat or cure any other health condition, including claims that the product is effective as a treatment or cure for cancer, including colon and breast cancer, prostate issues, asthma, and human immunodeficiency virus (HIV).

18. I will discuss what type of evidence is needed to substantiate these two types of claims in order, and then provide some additional comments on the value of anecdotal evidence.

### a. Evidence Required to Substantiate Claims that a Product Can Cure, Treat, or Prevent COVID-19

19. Based upon my professional training, knowledge, and experience, as discussed above, experts in the field would require that a claim that Earth Tea can treat, cure, or prevent

COVID-19 be supported by at least one, if not more, human clinical trials, in order to conclude that competent and reliable scientific evidence exists to support such claims. Experts in the field would require that the clinical trial has various critical features: the trial would have a written study protocol, be placebo-controlled (or, for a comparative claim, controlled against an alternative treatment option randomized), double-blinded, and randomized. The trial should also use an appropriate outcome measure and sample population, and have reliable data collected over an appropriate period of time. Finally, if there truly is an effect of the treatment the sample population must include enough subjects to make sure that if a difference is found the result was both statistically and clinically significant.

20. The clinical trial must be based on a written protocol. A well-designed clinical trial will be based on a written study protocol that describes the key features of the study, such as the key objectives, the methodology, the statistical analysis plan, the primary outcome measures, and the inclusion and exclusion criteria. In addition, clear and consistent records need to be kept while the trial is conducted to facilitate monitoring and re-analysis of data by independent authorities or other investigators.

21. The clinical trial should be placebo-controlled. For a clinical trial of a "new" product to demonstrate that the product has an effect, a treatment and control group is needed. A control group allows investigators to distinguish between real effects due to the intervention, and other changes, including those due to the mere act of being treated (the so-called "placebo effect"), the passage of time, or other changes in health. Thus, the control group provides a standard by which results observed in the treatment group can be evaluated, as it provides evidence of what is happening to a population that is not receiving the treatment over the same time period. The control group is typically approximately the same size as the treatment group,

and the control group should be similar in baseline characteristics to the treatment group. The control group should receive a placebo, which is an inactive product or treatment, in lieu of the intervention being tested. A placebo should be identical in size, appearance, and taste to the treatment product. Generally, no conclusions about efficacy can be drawn from a clinical trial that lacks a control group.

22. The clinical trial should be double-blinded, meaning that neither the investigators nor the study participants know whether the participant is in the treatment or the control group. Blinding helps ensure that participants' responses are not influenced by knowing which treatment they received. A so-called "open-label" study, in which both participants and investigators are aware of the treatment that the participants are being given, carries a risk of a phenomenon known as "expectation bias."[1] Expectation bias occurs when an individual's expectations about the outcome of an event or experiment influence the results of that event or experiment. In the context of a controlled clinical trial, expectation bias can occur when an investigator expects a treatment to be effective. To illustrate: if an investigator is aware of who is in the treatment group and who is in the control group, the investigator's expectations may lead them to pay closer attention to changes in participants who receive the treatment, leading to a biased interpretation of the results. Alternatively, an investigator may unintentionally convey their expectations to participants, who may in turn experience a (heightened) placebo effect, where they feel different because they believe they are receiving a treatment that will help them.

[1] *See, e.g.*, Janet B. Williams, et al. *P-640-The power of expectation bias*, EUROPEAN PSYCHIATRY (2012).

23. The clinical trial should be randomized along with proper allocation concealment. Randomization along with allocation concealment refers to a method by which study participants are assigned, randomly, either to the treatment group or the control group. The goal of this is to reduce the possibility that a researcher may consciously or unconsciously employ a selection bias regarding the group to which individual participants were assigned, and to help ensure that the baseline characteristics of each group are similar.

24. The clinical trial should use appropriate outcome measures. What an appropriate outcome measure is depends on the health condition or disease that the intervention seeks to study. The end points can be objective (e.g., blood work lab values) or subjective (pain levels) depending on the health condition being investigated. For COVID-19 pandemic developed, there are a number of different outcomes that should/could be evaluated – these include in no particular order:

a. overall mortality;

b. mortality from COVID-19;

c. symptomatic COVID-19 infection;

d. hospitalization for COVID-19 infection;

e. asymptomatic COVID-19 infection;

f. serious adverse events; and

g. overall adverse effects.

25. The trial must detail the participant selection criteria used, and help ensure both that the sample population is representative of the population at large, and appropriate for the claim at issue. For a claim that a product is effective in *treating or curing* a health condition, the sample population should suffer from the health condition in question, whereas for a claim that a

product can *prevent* a health condition, the study population must not at the time of enrollment have the health condition at issue.

26. The sample population must be sufficiently large – that is, it must enroll enough participants to be appropriately powered. To determine how many participants are needed to ensure statistical power, a power computation must be performed. If a trial does not enroll enough participants, or in other words, if the sample size is too small, its results may fail to establish an effect even when a treatment is in fact effective (a false negative).

27. The clinical trial must collect data over an appropriate period of time, which varies depending on if the trial is looking at treatment (likely 1–2 weeks) versus prevention (months to years).

28. The data must be subject to appropriate statistical analysis. After a clinical trial has been completed and all data has been collected, the data for the control and treatment groups must be compared through an appropriate statistical analysis. Simply a chance finding is typically only ruled out if results obtained by the treatment group have a statistically significant difference from the control group's result. This analysis is called a between-group analysis. A within-group analysis, where a researcher simply compares the treatment group participants before and after the intervention, has much less ability to determine cause and effect because the change observed within this group may be due to nothing more than a time and/or placebo effect. The threshold for statistical significance, commonly referred to as the "p" value, is typically considered less than or equal to 0.05 ($p \leq 0.05$). In addition, any statistically significant results must be reviewed for clinical significance. Clinical significance means that the size of the treatment effect would be considered clinically important. A result may be statistically significant, but not clinically significant.

**b. Evidence Required to Substantiate Claims that a Product Can Cure or Treat Other Health Conditions**

29. Based upon my professional training, knowledge, and experience, experts in the field of evidence appraisal would require that a claim that Earth Tea can treat or cure health conditions other than COVID-19 would also be supported by at least one human clinical trial, in order to conclude that competent and reliable scientific evidence exists to support such a claim. Experts in the field would require that the clinical trial contain the features listed in paragraphs 19-28 above.

30. Typically, a separate human clinical trial would be required for each health condition that is the subject of advertising claims – one cannot simply generalize from observing that a product is effective in treating one health condition to concluding that it is effective in treating a different health condition, even if the second condition bears some similarities to the first. Experts in the field would not accept results for studies of unrelated health conditions as competent and reliable evidence for all health conditions.

**c. Anecdotal "Evidence"**

31. Anecdotal evidence, such as reports from consumers, is insufficient to prove a product's efficacy. Such reports are not tested against a control group and are not blinded, and placebo effects and time effects are important especially among consumers who have bought an expensive product – they want to believe that the product will ameliorate their health condition, and they can be motivated to see and report an improvement. Subjective impressions of efficacy from open label trials, in which patients are not blinded, are therefore notoriously unreliable when it comes to establishing cause and effect.

32. In fact, some authors have suggested that "[p]airing the word 'anecdotal' with the word 'evidence' implies that anecdote is a form of evidence," and have suggested we should

detach the "word 'evidence' from 'anecdotal' and use a less judgemental word than evidence: information."[2] The plural of "anecdote" is not data – they are simply testimonials. This is why experts in the field require randomized controlled trials to properly assess efficacy.

## V. LITERATURE SEARCH

33. I searched PubMed, which is a search engine that primarily accesses the MEDLINE database of references and abstracts on life sciences and biomedical topics maintained by the U.S. National Library of Medicine, for relevant evidence on efficacy and safety, using the term "Earth Tea." I found no evidence other than the paper that was provided to me by the U.S. Department of Justice that I will discuss in paragraphs 35-44 below, and which is listed in Appendix A.

34. I also performed a general Google search and Google Scholar search, using the term "Earth Tea." I found no evidence other than the paper that I will discuss below, and an earlier unpublished summary of the same trial, both of which were also provided to me by the U.S. Department of Justice, and both of which are listed in Appendix A.

## VI. EVIDENCE APPRAISAL

35. I reviewed one published trial authored by Martin Sinclair et al., entitled "An Open Label, Multicentre, Multi-Dose, Single Arm Treatment Clinical Trial To Determine The Safety And Efficacy Of New Natural Health Drink Of Earth Tea In Human Adult, Patients With Mild Covid-19," published in the Journal of Pharmaceutical Negative Results in 2022. I further reviewed an earlier unpublished summary of the same trial, the transcript of and exhibits to Andrew Martin Sinclair's May 30, 2024 deposition, and various other materials produced by Mr.

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[2] R. Atenstaedt, *Should we continue pairing the term 'anecdotal' with evidence?*, BR. J. GEN. PRACT. (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6867225/.

Sinclair, including documents underlying the trial, customer reviews and affidavits, additional marketing claims relating to Earth Tea, and excel spreadsheets created by Mr. Sinclair relating to Earth Tea users. These materials, listed in Appendix A, were provided to me by the U.S. Department of Justice, and I understand that these materials comprise all substantiation materials provided by the defendants in discovery. As noted in paragraphs 33-34 above, my literature search did not produce any additional studies beyond these materials.

36. The evidence provided suffers from (1) critical methodological flaws, (2) extremely poor data collection and reporting, and (3) inconsistent data analysis. Furthermore, the trial was (4) published in a low-quality journal. As I explain more fully below, it is my opinion that this evidence does not constitute competent and reliable scientific evidence that Earth Tea can treat, cure, or prevent COVID-19.

37. The evidence suffers from the following critical methodological flaws:

a. The study lacks a control group. Without a control group that receives a placebo instead of the product being investigated for efficacy, it is impossible to know whether any change in the study population was caused by Earth Tea or some factor unrelated to the treatment. This methodological flaw alone means that this evidence cannot demonstrate Earth Tea's efficacy as a treatment or cure for COVID-19.

b. The trial was not blinded. Both the investigators and the participants were aware that they received the treatment—indeed, blinding is not possible without a control group that receives a placebo. Open-label studies such as the trial conducted by the defendant in this matter are notoriously unreliable.

c. The trial was not randomized. Although the authors state that the study participants were subject to randomization (page 7397), because there was no control

group, the participants could not be randomly assigned to treatment and control groups – there were no groups to randomly assign the participants to, as all participants were part of the treatment group. A lack of randomization is a further source of potential bias.

d. The trial's stated goals and associated participant selection criteria are unacceptably vague. The trial is intended as an investigation of the efficacy of Earth Tea as a treatment for "mild Covid-19," but the trial is simply a compilation of 15 anecdotal experiences of giving Earth Tea to 15 people with "mild Covid-19." The publication contains no description of what the investigators meant by mild COVID-19 - in contrast to moderate or severe COVID-19.

e. The outcome measures are not properly described. The authors state "In the analysis, patients showed a significant result in Clinical cure and Microbiological cure efficacy analysis on Day 02 (End of Study)" but the publication doesn't provide any actual data on outcomes other than stating "Safe and significant efficacy." The lack of well-defined outcome measures is by itself a sufficient basis for concluding that this trial does not provide evidence of Earth Tea's efficacy as a treatment or cure for COVID-19, as it leaves entirely open what, if anything, the end result of the trial was.

f. The design leaves open whether the observed effect is simply due to the passage of time. The trial refers to an initial visit ("Day 01") and a subsequent evaluation visit ("Day 02"), but the trial does not state how many days "Day 02 (evaluation)" was from "Day 01 (first dose)". The article states that the duration was 10 days, but it is unclear how long people received the tea, and when they were tested. The authors state "15 patients planned to be treated and analyzed for up to 10 days" but the article doesn't specify when they were assessed or how long they were treated. Without this clarity of

the research process, it is impossible to assess the quality of the results or interpret the findings. Furthermore, the participants were enrolled if they were symptomatic up to 7 days before the beginning of the trial (page 7397). Given that symptoms can appear anywhere from 2-14 days after infection,[3] and most people recover from COVID-19 infections without medical intervention in the course of 1-2 weeks after infection, any improvement observed may be due simply to the passage of time regardless of the exact number of days between the two visits.[4] These issues alone make this paper virtually useless as an evidence source for evaluating efficacy and toxicity.

g. The trial's population size is small. The population consists of 15 test subjects. Properly designed studies of medical interventions designed to treat COVID-19 enrolled would need to enroll hundreds of test subjects (and if it was a prevention study it would require thousands of test subjects).

38. The trial suffers from extremely poor data collection and reporting. This paper is one of the most poorly written publications I have ever read. It contains many spelling and grammatical errors and some of the charts and the figures don't make any sense whatsoever. As a result, it is virtually impossible to interpret its results. To illustrate:

a. As noted above, on page 7397, the authors incorrectly state that the trial was randomized, even though it could not be, because there was no control group.

b. The trial is described as "multicenter" on page 7396, but on page 7397, the authors directly contradict this statement by listing only a single test location, namely,

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[3] *Symptoms of COVID-19*, CENTERS FOR DISEASE CONTROL AND PREVENTION (updated Oct. 26, 2022), https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.htm.

[4] *See, e.g.*, P.K. Drain et al., *Duration of viral infectiousness and correlation with symptoms and diagnostic testing in non-hospitalized adults during acute SARS-CoV-2 infection: A longitudinal cohort study*, J. CLIN. VIROL. (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9981266/.

"Primary Health Care Centre, Kunigal, Karnataka, India."

c. At page 7401, the publication's Conclusion also indicates that "patients displayed a substantial difference between their enrollment visit on day one and their evaluation visit on day two." Unfortunately, the publication provides no data about this.

d. At page 7400, Graph-1 of the publication states: "The Nagative [sic] results shown after or before 48 Hrs." This phrase doesn't make sense. It is unclear whether the tests were done before or after 48 hours.

e. At page 7401, the publication's Conclusion states: "Additionally, the patients weren't very concerned about any potential side effects, dosage restrictions, or their regular lives." The publication provides no indication of how this was assessed and I have no idea what it means that "patients weren't very concerned about any potential side effects." This problem is compounded because the publication contains no other reporting of side effects.

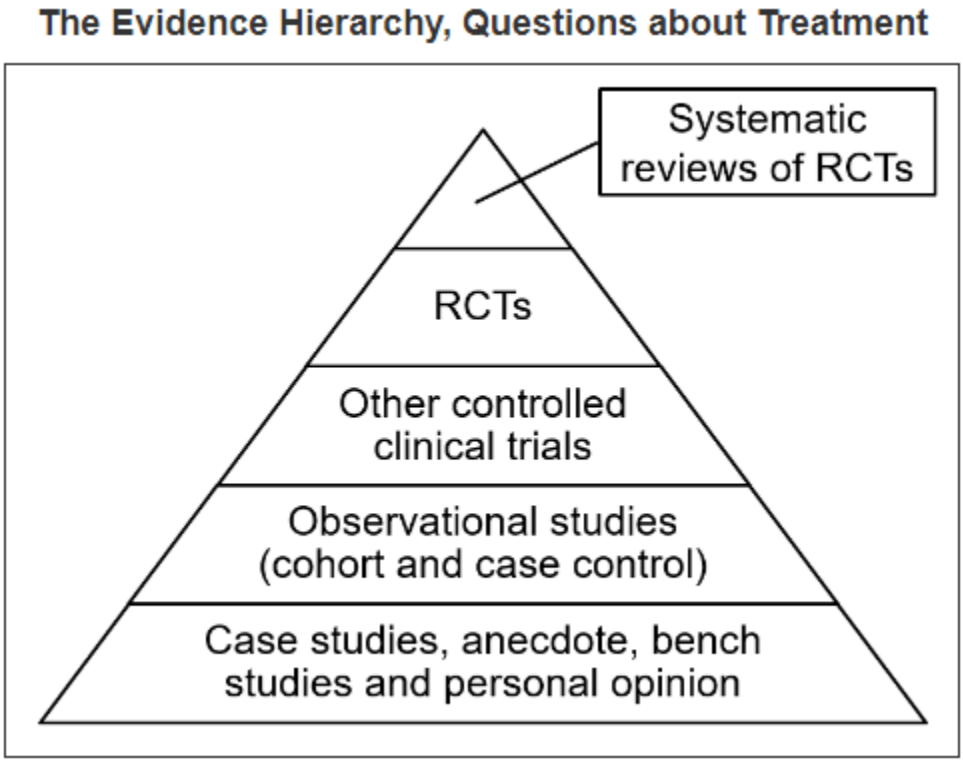
39. The data analysis is unintelligible. The authors state "In the analysis, patients showed a significant result in Clinical cure and Microbiological cure efficacy analysis on Day 02 (End of Study)" but the publication doesn't contain any actual data on outcomes other than stating "Safe and significant efficacy." In addition, at page 7401, the publication's Conclusion refers to: "The analysis showing that the product is statistically effective." No comparative statistics were done because there was no comparator (no control group that received a placebo instead of an actual treatment) so one can't say that the results were statistically effective. In addition, statistics don't prove something is effective; all they do is help us rule out that a finding was simply due to chance. You can have statistical differences but the size of these differences might be clinically unimportant. Unfortunately, as noted above, in this case there was no control

group with which to compare the effect of Earth Tea.

40. The trial was published in a low-quality journal. It is published in the *Journal of Pharmaceutical Negative Results*, a non-indexed journal. Non-indexed journals lack stringent publication requirements, including clear and adequate peer-review processes. The journal also has a very low impact factor, namely, an impact factor rating of <1. The impact factor of a journal is a measure of the frequency with which the "average article" in a journal has been cited in a particular year. In layman's terms, this means that the journal in which the paper was published is not a journal that scientists typically rely on to inform their work.

41. Overall, this is a very poorly designed, run and reported "clinical trial". It provides no reliable evidence for the effectiveness or tolerability of Earth Tea. It is simply 15 incomplete and confusingly reported case studies of 15 patients with mild COVID-19 who received Earth Tea for some duration. Even if it was well run and well-reported it would still fail to provide evidence for the efficacy of Earth Tea, and would typically fall into the lowest or second lowest category of evidence. See Figure 1 below.

**Figure 1**




https://libguides.mssm.edu/ebm/hierarchy#:~:text=Still%2C%20most%20agree%20that%20current,experience%20are%20at%20the%20bottom

42. An example of the problem inherent in a "trial" like this is that if you took 100 people with a cold/flu and gave them a placebo for a week to 10 days, it is likely that 100% would be better after a week to 10 days. That doesn't in any way mean that a placebo works for the common cold in 100% of people. Typically, mild COVID-19 runs a course similar to that of a bad cold or the flu – the symptoms resolve in roughly 7-10 days, so the fact that these people recovered cannot be attributed to Earth Tea. It is my opinion that this evidence does not provide competent and reliable scientific evidence that Earth Tea is effective in treating or curing

COVID-19.

43. Furthermore, the evidence doesn't look at prevention of COVID-19. To evaluate whether Earth Tea can prevent infection with COVID-19, a trial's participants would need to not be infected at the beginning of the trial, and then be observed over a sufficiently long period of time. Since the participants in this trial all had tested positive for COVID-19 at the beginning of the trial, it simply cannot tell us anything about whether Earth Tea is effective in preventing infection with COVID-19. No other studies were found that assessed whether Earth Tea is effective at preventing COVID-19. Therefore, I conclude that there is no competent and reliable scientific evidence that Earth Tea is effective in preventing COVID-19.

44. I also reviewed several consumer testimonials concerning Earth Tea provided to me by the U.S. Department of Justice. As explained in paragraphs 31-32, anecdotal "evidence," such as consumer testimonials, cannot provide competent and reliable scientific evidence of a product's efficacy.

## VII. REVIEW OF DEFENDANT SINCLAIR'S DEPOSITION

45. I have also reviewed the deposition given in this case by Andrew Sinclair on 5/30/2024, and the exhibits to the deposition. My analysis of them is broken down into a number of key points/issues:

(1) Background training and knowledge;

(2) Design and interpretation of clinical trials;

(3) The extent of the scientific knowledge around Earth Tea; and

(4) The interpretation of the Earth Tea trial.

### (1) Background training and knowledge

46. It is clear from the deposition that Mr. Sinclair has no training in science nor in clinical

trial design as he states almost all his scientific knowledge comes from personal experience along with searching and reading things he has found on the internet. Tr. 30:19-21.

47. He states he is "self-taught" which he describes as being almost the same as "someone teaching you." Tr. 31:12-13.

48. Mr. Sinclair believes Earth Tea is a product that provides "immune support." Tr. 80:5.

49. His background knowledge of the immune system is minimal at best and often incorrect. He also seems to think he has a working knowledge of the immune system, when he clearly does not.

50. For example, while he does understand the immune system is important, he claims the immune system doesn't cause rheumatoid arthritis. Tr. 191:3-192:17; 193:7-21. We know that rheumatoid arthritis is an autoimmune disease caused by an overactive immune system.

51. He also states the immune system is in control of everything in your body including "blinking" your eyes. Tr. 30:10-11. This is clearly not true as blinking, in general, is controlled by the autonomic nervous system.

**(2) Design and interpretation of clinical trials**

52. Over the last 100 years, researchers have developed the scientific method as a way of seeking answers to questions by observing and asking scientific questions and then seeking answers to these questions by doing properly designed tests and experiments. Having a knowledge of this method is essential when one is developing a new medical treatment. There are also many essential aspects to be knowledgeable about when it comes to the design and interpretation of clinical trials.

53. Mr. Sinclair seems to not understand, almost at all, some very basic terms (listed below) that are fundamental to trial design and interpretation. He either has no idea what the following terms mean, or misinterprets what they really mean:

a) A control group and the need for a control group. Tr. 267:20-268:5.

b) Placebo and the need for a placebo. Tr.268:6-20.

c) Randomization and the need for randomization. Tr. 269:12-25.

d) Blinding and the need for blinding. Tr. 270:2-6.

e) Power computation. Tr. 270:7-13.

f) Primary outcome measure. Tr. 270:14-23.

g) Open label design. Tr. 272:11-14.

h) Single arm studies. Tr. 273:15-24.

**(3) The extent of the scientific knowledge around Earth Tea**

54. Mr. Sinclair acknowledges the extent of his scientific evidence to support the efficacy of Earth Tea for different medical conditions is primarily limited to his personal experience and customer feedback. Tr. 214:5-217:16; 228:2-233:11.

55. He is also clearly aware that no other researchers or health care providers have evaluated or suggested that Earth Tea is effective for any disease or ailment other than COVID-19. Tr. 219:13-220:8.

56. He is unaware of any scientists who believe Earth Tea is effective at preventing, treating or curing COVID-19. Tr. 298:21-299:4.

57. He testified that Earth Tea is not generally accepted by scientific experts as safe and effective against COVID-19 or any other disease. Tr. 323:10-324:7.

58. He knows there aren't any scientific studies that have shown Earth Tea is safe and

effective against any disease. Tr. 324:2-13.

59. He also acknowledges there are no published studies evaluating Earth Tea as a treatment or cure for any disease or health condition other than the "trial" he has done relating to COVID-19. Tr. 324:8-19.

**(4) The interpretation of the Earth Tea trial**

60. Mr. Sinclair acknowledges the clinical trial he sponsored is the only attempt to evaluate Earth Tea in a clinical setting. Tr 259:3-16.

61. He also believes if 50 people try Earth Tea for the same ailment and they improve, that is enough to know Earth Tea is effective against the ailment. Tr. 5:8-197:10. This clearly shows he does not sufficiently understand the natural history of a condition like COVID-19 nor why one needs a control group of some sort to control for issues such as the placebo effect/natural history and the possibility that the improvement of individuals from ailments may have nothing to do with Earth Tea. Even the investigators of the trial recommended, as would anyone knowledgeable about clinical trial design, a study design that included a larger study population, Tr. 260:11-261:5, and a placebo control. Tr. 268:12-20. Mr. Sinclair rejected these suggestions in order to reduce the trial's costs.

62. The investigator who conducted the trial told Mr. Sinclair he couldn't use the trial results to say in Earth Tea's labelling that it is a cure or treatment for COVID-19, and Mr. Sinclair now understands that labeling includes social media and website posts. Tr. 300:6-302:25.

63. There were also some questionable deviations from the trial protocol, as three of the 15 before and after PCR tests from the trial are not of the same people. Tr. 290:6-296:4 (Exhibits 61-63).

64. In addition, the investigators did not follow the study's protocol as they re-tested

one of the study participants at a later point in time based on a request from Mr. Sinclair. Tr. 308:1-24.

65. In conclusion, Mr. Sinclair's testimony indicates that he very strongly believes the key evidence for the benefit of Earth Tea is what he has "seen" when he and others have taken it for COVID-19. Tr. 233:8:11. The fundamental flaw in this thought process is that, in most cases, COVID-19 is a self-limiting condition and most people get better without any treatment. Because of this natural history, it is essential that determining the efficacy of any product for COVID-19 requires multiple well-designed placebo-controlled trials large enough to identify a clinically important difference, should one exist.

66. None of his testimony in anyway changes my previous evaluation of the evidence. Mr. Sinclair's background training and knowledge, and understanding of design and interpretation of clinical trials, is clearly far too rudimentary for him to be able to, despite whatever intentions, develop or evaluate the potential benefit of any product that would be used to improve human health.

## VII. CONCLUSION

67. As detailed in the foregoing, the materials I reviewed and the broad searches I conducted did not reveal any reliable scientific evidence that would substantiate any health claims for Earth Tea. In particular, there is no competent and reliable scientific evidence that Earth Tea:

a. Prevents COVID-19;

b. Treats the symptoms of COVID-19;

c. Cures COVID-19;

d. Leads to recovery from COVID-19 within 48 hours;

e. Is 100% effective in preventing hospitalization from COVID-19;

f. Is more effective than a vaccine in preventing hospitalization from COVID-19;

g. Is clinically proven effective to treat and cure COVID-19;

h. Is clinically proven to cure COVID-19 in 48 hours; or

i. Is effective in treating or preventing any other disease.

68. Regarding the single published paper of Earth Tea, given its many deficiencies, noted above, it is completely inadequate to substantiate any claims that Earth Tea is effective against COVID-19. Anecdotal evidence about the efficacy of Earth Tea, including testimonials from customers, is also inadequate to substantiate any claims that Earth Tea is effective against any disease. The only way to properly test the efficacy of a product like Earth Tea against any medical condition would be to do a well-designed and reported randomized, controlled human clinical trial ("RCT") of Earth Tea versus placebo in patients with whatever medical condition is being assessed. When it comes to cause-and-effect determinations, RCTs are considered the next to highest level of evidence (the highest level being multiple clinical trials). The single published trial discussed above does not qualify as an RCT, and I am unaware of any RCTs of Earth Tea.

69. I may offer other areas of testimony as the evidence develops, and in rebuttal to any expert reports submitted by the defendant. I also reserve the right to supplement this report.

Dated: July 26, 2024.

James P. McCormack, *BSc (Pharm), Pharm.D.*
Professor, Faculty of Pharmaceutical Sciences
University of British Columbia, Vancouver, BC

**Appendix A. Materials Considered**

1) I reviewed all of the roughly 300 social media and website posts relating to Earth Tea provided by the U.S. Department of Justice:

USA-B4B00000015

USA-B4B00000016

USA-B4B00000035

USA-B4B00000057

USA-B4B00000066

USA-B4B00000097

USA-B4B00000105

USA-B4B00000213

USA-B4B00000226

USA-B4B00000309

USA-B4B00000397

USA-B4B00000426

USA-B4B00000459

USA-B4B00000474

USA-B4B00000545

USA-B4B00000557

USA-B4B00000567

USA-B4B00000594

USA-B4B00000614

USA-B4B00000615

USA-B4B00000650

USA-B4B00000652

USA-B4B00000656

USA-B4B00000658

USA-B4B00000860

USA-B4B00000992

USA-B4B00001411

USA-B4B00001417

USA-B4B00001452

USA-B4B00001453

USA-B4B00001456

USA-B4B00001457

USA-B4B00001484

USA-B4B00001497

USA-B4B00001518

USA-B4B00001520

USA-B4B00001532

USA-B4B00001557

USA-B4B00001561

USA-B4B00001562

USA-B4B00001569

USA-B4B00001582

USA-B4B00001584

USA-B4B00001634

USA-B4B00001649

USA-B4B00001650

USA-B4B00001660

USA-B4B00001665

USA-B4B00001691

USA-B4B00001729

USA-B4B00001731

USA-B4B00001739

USA-B4B00001743

USA-B4B00001750

USA-B4B00001803

USA-B4B00001821

USA-B4B00001833

USA-B4B00001873

USA-B4B00001884

USA-B4B00001898

USA-B4B00001931

USA-B4B00001939

USA-B4B00001944

USA-B4B00001988

USA-B4B00003138

USA-B4B00003139

USA-B4B00003140

USA-B4B00003141

USA-B4B00003143

USA-B4B00003145

USA-B4B00003146

USA-B4B00003148

USA-B4B00003149 - USA-B4B00003150

USA-B4B00003151

USA-B4B00003152 - USA-B4B00003154

USA-B4B00003194 - USA-B4B00003215

USA-B4B00003219

USA-B4B00003221 - USA-B4B00003226

USA-B4B00003228

USA-B4B00003230

USA-B4B00003231

USA-B4B00003241

USA-B4B00003243

USA-B4B00003244

USA-B4B00003259

USA-B4B00003266

USA-B4B00003267

USA-B4B00003271

USA-B4B00003273

USA-B4B00003274

USA-B4B00003275

USA-B4B00003282

USA-B4B00003286

USA-B4B00003288

USA-B4B00003290

USA-B4B00003300

USA-B4B00003304 - USA-B4B00003311

USA-B4B00003314 - USA-B4B00003359

USA-B4B00003361 - USA-B4B00003397

USA-B4B00003398 - USA-B4B00003407

USA-B4B00003413

USA-B4B00003417 - USA-B4B00003494

USA-B4B00003497

USA-B4B00003504

USA-B4B00003507 - USA-B4B00003526

USA-B4B00003527

USA-B4B00003532

USA-B4B00003533

USA-B4B00003534

USA-B4B00003536

USA-B4B00003537

USA-B4B00003538

USA-B4B00003540

USA-B4B00003541

USA-B4B00003542

USA-B4B00003546 - USA-B4B00003552

USA-B4B00003555

USA-B4B00003564

USA-B4B00003566

USA-B4B00003588

USA-B4B00003595 - USA-B4B00003600

USA-B4B00003604

USA-B4B00003625

USA-B4B00003630

USA-B4B00003639

USA-B4B00003647

USA-B4B00003650

USA-B4B00003652

USA-B4B00003657

USA-B4B00003660

USA-B4B00003671

USA-B4B00003675

USA-B4B00003680

USA-B4B00003689

USA-B4B00004856

USA-B4B00004859

USA-B4B00004860

USA-B4B00004862

USA-B4B00004869

USA-B4B00004871

USA-B4B00004873

USA-B4B00004901

USA-B4B00004906

USA-B4B00004907

USA-B4B00004909 - USA-B4B00004914

USA-B4B00004917 - USA-B4B00004920

USA-B4B00004922

USA-B4B00004924

USA-B4B00004927

USA-B4B00004930

USA-B4B00004935

USA-B4B00004945

USA-B4B00004970

USA-B4B00004976

USA-B4B00004983

USA-B4B00005002

USA-B4B00005024

USA-B4B00005034

USA-B4B00005045

USA-B4B00005053

USA-B4B00005066

USA-B4B00005068

USA-B4B00005069

USA-B4B00005096

USA-B4B00005097

USA-B4B00005115

USA-B4B00005116

USA-B4B00005135

USA-B4B00005136

USA-B4B00005138

USA-B4B00005145

USA-B4B00005163

USA-B4B00005165

USA-B4B00005167

USA-B4B00005170

USA-B4B00005173

USA-B4B00005181

USA-B4B00005183

USA-B4B00005186

USA-B4B00005187

USA-B4B00005190

USA-B4B00005191

USA-B4B00005198

USA-B4B00005201

USA-B4B00005208

USA-B4B00005211

USA-B4B00005214

USA-B4B00005218

USA-B4B00005221

USA-B4B00005222

USA-B4B00005224

USA-B4B00005230 - USA-B4B00005236

USA-B4B00005241

USA-B4B00005244

USA-B4B00005275

USA-B4B00005310

USA-B4B00005449

USA-B4B00005740

USA-B4B00005813

USA-B4B00005830

USA-B4B00005836

USA-B4B00005850

USA-B4B00006079

USA-B4B00006081

USA-B4B00006083

USA-B4B00006088

USA-B4B00006114

USA-B4B00006119

USA-B4B00006120

USA-B4B00006122

USA-B4B00006131

USA-B4B00006142

USA-B4B00006164

USA-B4B00006193

USA-B4B00006317

USA-B4B00006319

USA-B4B00006388

USA-B4B00006400

USA-B4B00006401

USA-B4B00006426

USA-B4B00006429

USA-B4B00006462

USA-B4B00006464

USA-B4B00006475

USA-B4B00006499

USA-B4B00006510

USA-B4B00006513

USA-B4B00006544

USA-B4B00006551

USA-B4B00006563

USA-B4B00006589

USA-B4B00006592

USA-B4B00006599

USA-B4B00006605

USA-B4B00006616

USA-B4B00006646

USA-B4B00006649

USA-B4B00006655

USA-B4B00006660

USA-B4B00006681

USA-B4B00007248

USA-B4B00007249

2) I reviewed the one paper authored by Martin Sinclair, An Open Label, Multicentre, Multi-Dose, Single Arm Treatment Clinical Trial To Determine The Safety And Efficacy Of New Natural Health Drink Of Earth Tea In Human Adult, Patients With Mild Covid-19 written by Sinclair M *et al.* in the Journal of Pharmaceutical Negative Results 2022.

3) I reviewed the earlier unpublished summary of the aforementioned trial of Earth Tea.

4) I reviewed additional documents produced by Martin Sinclair, including documents underlying the aforementioned clinical trial:

B4B-USA-00000065

B4B-USA-00000066

B4B-USA-00000067

B4B-USA-00000068

B4B-USA-00000069

B4B-USA-00000070

B4B-USA-00000071

B4B-USA-00000072

B4B-USA-00000073

B4B-USA-00000074

B4B-USA-00000075

B4B-USA-00000076

B4B-USA-00000077

B4B-USA-00000078

B4B-USA-00000079

B4B-USA-00000080

B4B-USA-00000081

B4B-USA-00000082

B4B-USA-00000083

B4B-USA-00000084

B4B-USA-00000085

B4B-USA-00000086

B4B-USA-00000087

B4B-USA-00000088

B4B-USA-00000089

B4B-USA-00000290

B4B-USA-00000291

B4B-USA-00000292

B4B-USA-00000293-0294

B4B-USA-00000296-0324

B4B-USA-00000331-0332

B4B-USA-00000333-0334

B4B-USA-00000335-0336

B4B-USA-00000337-0338

B4B-USA-00000339-0340

B4B-USA-00000341-0342

B4B-USA-00000343-0344

B4B-USA-00000345-0346

B4B-USA-00000376

B4B-USA-00000421

B4B-USA-00000422

B4B-USA-00000423-0435

B4B-USA-00000436-0448

B4B-USA-00000449-0452

B4B-USA-00000453

B4B-USA-00000454

B4B-USA-00000455

B4B-USA-00000456

B4B-USA-00000457-0469

B4B-USA-00000470

B4B-USA-00000471-0474

B4B-USA-00000475

B4B-USA-00000476-0506

B4B-USA-00000507-0509

B4B-USA-00000510-0513

B4B-USA-00000514-0518

B4B-USA-00000816-0817

B4B-USA-00001803

B4B-USA-00001931

B4B-USA-00002686

B4B-USA-00003413

B4B-USA-00007360

5) I searched PubMed and also did a general Google search and a Google scholar search.

6) I reviewed the May 30, 2024 deposition of Andrew Martin Sinclair, and the exhibits to the deposition.

7) I reviewed the website:

https://oxford-review.com/evidence-based-practice-essential-guide/

8) I reviewed the website:

https://libguides.mssm.edu/ebm/hierarchy#:~:text=Still%2C%20most%20agree%20that

%20current,experience%20are%20at%20the%20bottom

9) I also reviewed all other sources of data or information that I cite in this expert report.

**Appendix B. Publications from the last 10 years**

1. Allan GM, Nouri F, Korownyk C, Kolber MR, Vandermeer B, McCormack J. Agreement among cardiovascular risk calculators. Circulation 2013;127:1948-56

2. McCormack J, Vandermeer B, Allan GM. How confidence intervals become confusion intervals. BMC Med Res Methodol. 2013 Oct 31;13:134. doi: 10.1186/1471-2288-13-134

3. Allan GM, Nouri F, Korownyk C, Kolber MR, Vandermeer B, McCormack J. Response to letters regarding "agreement among cardiovascular disease risk calculators". Circulation 2013;128 :e430. doi: 10.1161/CIRCULATIONAHA.113.005511

4. McCormack J, Banh HL, Allan GM. Refining the American guidelines for prevention of cardiovascular disease. Lancet 2014;9917:598-9

5. Lindblad AJ, Garrison S, McCormack J. Testing vitamin D levels. Can Fam Phys 2014;60:351

6. Allan GM, Garrison S, McCormack J. Comparison of cardiovascular disease risk calculators. Curr Opin Lipidol 2014;25:254-65

7. Martin SA, McCormack JP, Newman DH. Letter - Changes in Diabetes-Related Complications in the United States. N Engl J Med 2014;371:284

8. McCormack JP. Blood Pressure Medicines for Five Years to Prevent Death, Heart Attacks, and Strokes. thennt.com 2014 http://www.thennt.com/nnt/anti-hypertensives-to-prevent-death-heart-attacks-and-strokes/

9. McCormack JP, Chmelicek JT. Generic versus brand name: the other drug war. Can Fam Phys October 2014 60: 911

10. Korownyk C, Kolber MR, McCormack J, Lam V, Overbo K, Cotton C, Finley C, Turgeon RD, Garrison S, Lindblad AJ, Banh HL, Campbell-Scherer D, Vandermeer B, Allan GM. Televised medical talk shows-what they recommend and the evidence to support their recommendations: a prospective observational study. BMJ 2014 Dec 17;349:g7346. doi: 10.1136/bmj.g7346.

11. Caulfield T, Clark MI, McCormack JP, Rachul C, Field CJ. Representations of the health value of vitamin D supplementation in newspapers: media content analysis. BMJ Open 2014;4:e006395 doi:10.1136/bmjopen-2014-006395

12. Korownyk C, Kolber MR, McCormack J, Allan M. Rapid Response to letters regarding "Televised Medical Talk Shows" BMJ April 02, 2015

13. Korownyk C, Kolber MR, McCormack J, Allan M. Rapid Response to letters regarding "Televised Medical Talk Shows" BMJ June 2015

14. McCormack JP, Martin SA, Newman DH. Comment on Inzucchi et al - Management of Hyperglycemia in Type 2 Diabetes, 2015: A Patient-Centered Approach. Diabetes Care 2015;38:e141–e142 | DOI: 10.2337/dc15-0074

15. McCormack J, Malhotra A, Newman D. Challenging treatment thresholds. Prescriber 2015;5:5-7

16. Allan GM, Nouri F, Korownyk C, Kolber MR, Vandermeer B, McCormack J. Variation among cardiovascular risk calculators in relative risk increases with identical risk factor increases. BMC Research Notes 2015;8:417

17. McCormack JP. Cardiovascular outcomes and blood pressure, glucose, and cholesterol numbers. UBC CPD – This Changed My Practice 2015 http://thischangedmypractice.com/cv-outcomes-and-bp-glc-chol/

18. Lehman R, Tejani AM, McCormack J, Perry T, Yudkin JS. Ten Commandments for patient-centred treatment. British Journal of General Practice 2015;65:532-3

19. Allan GM, Lindblad AJ, Comeau A, Coppola J, Hudson B, Mannarino M, McMinis C, Padwal R, Schelstraete C, Zarnke K, Garrison S, Cotton C, Korownyk C, McCormack J, Nickel S, Kolber MR. Simplified lipid guidelines: Prevention and management of cardiovascular disease in primary care. Can Fam Phy 2015;61:857-67

20. McCormack J, Malhotra A, Newman D. It's Time for Shared Decision Making in Cardiovascular Risk Factor Modification. Cardiol Pharmacol 2015;4:3-4

21. Allan GM, Cranston L, Lindblad A, McCormack J, Kolber MR, Garrison S, Korownyk C. Vitamin D: A Narrative Review Examining the Evidence for Ten Beliefs. J Gen Int Med 2016;31:780-91

22. McCormack JP. If We Don't, Somebody Else Will. UBC PSSJ 2016;3:3

23. Lesser LI, McCormack JP. Financial incentives and cholesterol levels. JAMA 2016;315:1657-8

24. Yudkin JS, Kavanagh J, McCormack JP. Guidelines for treating risk factors should include tools for shared decision making. BMJ 2016;353:i3147 1-3

25. Loewen P. Gerber P, McCormack J, MacDonald G. Design and implementation of an integrated medication management curriculum in an entry-to-practice Doctor of Pharmacy Programme. Pharmacy Education 2016;16:122-30

26. McCormack JP, McAlister FA, Kolber MR. Higher medication doses in heart failure. Can Fam Phy 2017;63:e20

27. Allan GM, Finley CR, McCormack J, Kumar V, Kwong S, Braschi E, Korownyk C, Kolber MR, Lindblad AJ, Babenko O, Garrison S. Are potentially clinically meaningful benefits misinterpreted in cardiovascular randomized trials? A systematic examination of statistical significance, clinical significance, and authors' conclusions. BMC Medicine 2017;15:58-68

28. Allan GM, McCormack J, Korownyk C, Lindblad AJ, Garrison S, Kolber MR. The future of guidelines: Primary care focused, patient oriented, evidence based and simplified. Maturitas 2017:95:61–2

29. McCracken R, McCormack J, McGregor MJ, Wong S T, Garrison S. Associations between polypharmacy and treatment intensity for hypertension and diabetes: a cross-sectional study of nursing home patients in British Columbia, Canada BMJ Open 2017;7:e017430. doi: 10.1136/bmjopen-2017-017430

30. Korownyk C, McCormack J, Kolber MR, Garrison S, Allan GM. Competing demands and opportunities in primary care. Canadian Family Physician 2017;63:664-8

31. Allan GM, Korownyk C, Kolber MR, Garrison S, McCormack J Nickel S, Lindblad A. What's in your stocking? Evidence around Santa Claus. Canadian Family Physician 2017;63:942

32. Allan GM, Ramji J, Perry D, Ton J, Beahm NP, Crisp N, Dockrill B, Dubin RE, Findlay

T, Kirkwood J, Fleming M, Makus K, Zhu X, Korownyk C, Kolber MR, McCormack J, Nickel S, Noël G, Lindblad AJ. Simplified guideline for prescribing medical cannabinoids in primary care. Can Fam Physician 2018;64:00-0

33. McCormack JP, Korownyk C. Effectiveness of antidepressants – Invited Editorial. BMJ 2018;360:k1073 doi: 10.1136/bmj.k1073 (Published 9 March 2018)

34. McCormack JP. Shared decision making and high blood pressure (letter). CPJ - April 2, 2018 https://doi.org/10.1177/1715163518767941

35. McCormack J, Elwyn G. Shared decision is the only outcome that matters when it comes to evaluating evidence-based practice. BMJ Evidence-Based Medicine 2018;23:137-9

36. Turgeon RD, Kolber MR, Loewen P, Ellis U, McCormack JP. Higher versus lower doses of ACE inhibitors, angiotensin-2 receptor blockers and beta-blockers in heart failure with reduced ejection fraction: Systematic review and meta-analysis. PLOS 2019 – https://doi.org/10.1371/journal.pone.0212907

37. McCormack J. Is there adequate evidence for quadrupling inhaled corticosteroid doses? Can Fam Physician. 2019;65: 313-4

38. McCormack JP, Holmes D. Your results may vary: a precise discussion about the imprecision of medical measurements. BMJ 2020;368 doi:

https://doi.org/10.1136/bmj.m149 BMJ COVER STORY

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